REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars.

1. In the claims

As shown in the foregoing amendment to the claims, the claims have been amended to more clearly point out the subject matter for which protection is sought.

A. Claims 13-20, 22 and 23

Claim 13 is amended to recite a flexible liner "being vapor impervious." Support for this amendment is found at least in Figures 4B and 7 as well as in paragraphs [0012], [0013], [0027], [0030] and [0033] of the accompanying description in the specification. The liner 16 is shown in cross-section in Figs. 4B and 7 and has a solid layer with no pores. The solid non-porous layer is inherently impervious to vapors and gasses. Additionally, the continuously cured elastomer structure described in the above mentioned paragraphs in the specification is also inherently impervious to vapors or gasses.

In particular, reference is made in paragraph [0033] to U.S. patent 6,485,776 (Janusson et al.) to describe the method used to form the liner. The Janusson et al. patent describes a method of forming a prosthetic suction liner, which must not allow the passage of vapors or gasses in order to properly function as a prosthetic suction liner (col. 1, lines 55-60). The Janusson et al. patent further describes coating the inner surface of a fabric tube with a continuous, thin cured silicone elastomer (col. 2, lines 9-10). This method provides a continuous sealing film of elastomer on one surface of the fabric (col. 2, lines 51-60). This continuous sealing film is impermeable to air (col. 6, lines 60-63).

Since the originally filed application includes reference to a liner having a surface of continuously cured elastomer which creates a sealing film of elastomer that is impermeable to air, no new matter is added by the amendments to the claims.

Claims 14-20, 22 and 23 are left unchanged.

B. Claims 24 and 25

Claim 24 is amended to recite "that the liner is vapor impervious." No new matter is added since support for this amendment, as discussed above in section A, is found in at least in Figures 4B and 7 as well as paragraphs [0012], [0013], [0027], [0030] and [0033] of the accompanying description in the specification.

Claim 25 remains unchanged

Entry of the amendment of the claims is respectfully requested in the next Office communication.

2. Rejection of claims 13-20 and 22 under 35 U.S.C. § 102(e) as being anticipated by U.S. publication 2004/0002671 (Reaux)

Reconsideration of this rejection, in light of the amendment to claim 13 is respectfully requested on the basis that the Reaux publication does not disclose every limitation of pending claims 13-20 and 22.

The Reaux publication does not disclose a liner that is vapor impervious as required by amended claim 13. The rejection relies on the disclosure in the Reaux publication of a liner that is "fluid repellant or breathable, allowing passage of water vapor" to show a liner that is non-porous. Moreover, the rejection states that the liner in the Reaux publication "can repel water and therefore [is] non-porous" (page 2, line 23).

While the applicants disagree that the Reaux publication discloses a non-porous liner, for the reasons discussed in the Request for Reconsideration filed on February 27, 2006, there is certainly no disclosure in the Reaux publication that the liner is impervious to vapors and gasses as required by amended claim 13. In fact, there is actually disclosure in the Reaux publication of exactly the opposite; the liner of the Reaux publication can be breathable (paragraph [0016]).

One advantage of the non-porous vapor and gas impervious liner of claim 13 is that it prevents irritating vapors from the curing resin from contacting the skin. This important feature allows the casting to be made without causing irritation or

rashes to the underlying skin of the user. Additionally, the skin of the user is not contacted by the resin, and therefore, no cleaning of the user's underlying skin is required following the removal of the casting.

Further, the liner of claim 13 is not meant to be worn for any extended period of time, but only for a sufficient length of time so that the activatable hardenable compound sets. Since the liner will only be in place for short periods of time, there is no concern for wicking away the wearer's perspiration or for keeping the wearer's skin dry.

In contrast, given the intended use of the liner of the Reaux publication as a liner for casts and splints meant to be worn for weeks or months at a time, a liner that is impervious to vapors and gasses would trap perspiration between the skin of the user and the liner, causing discomfort, odors and possibly rashes. This situation would be unacceptable since the liner of the Reaux publication is meant to be used in a cast or splint that will be worn for weeks or months at a time. The liner disclosed in the Reaux publication must allow the passage of vapors or gasses in order to wick away the perspiration of the person wearing the cast or splint, or in order to keep the user's skin dry.

As another advantage, the non-porous vapor and gas impervious liner of claim 13 allows for smooth surfaced positive molds to be made. If the liner were porous and allowed for the passage of vapors and gasses therethrough, a texture would be formed on the positive mold and would need to be sanded, ground, or polished off prior to the use of the positive mold.

Since the liner disclosed in the Reaux publication is porous and allows the passage of vapors or gasses therethrough, the Reaux publication does not disclose every limitation of claims 13-20 and 22. Therefore, withdrawal of this rejection is respectfully requested.

3. Rejection of claims 24 and 25 under 35 U.S.C. § 103(a) as being unpatentable over the Reaux publication

Reconsideration of this rejection, in light of the amendment to claim 24, is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness.

A. The Reaux publication fails to disclose every limitation of the claims

Reconsideration of this rejection, in light of the amendment to claim 24, is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness because the Reaux publication does not disclose every limitation of pending claims 24 and 25.

The Reaux publication does not disclose a liner having a continuously cured silicone elastomeric layer such that the liner is vapor impervious as required by amended claim 24. As discussed above in section 2, the liner disclosed in the Reaux publication allows the passage of vapors or gasses therethrough in order to wick away perspiration from the user, or to keep the user's skin dry. The rejection also acknowledges that the liner of the Reaux publication does not have a continuously cured silicone elastomeric layer (page 3, lines 16-17).

A *prima facie* case of obviousness cannot stand, since the Reaux publication does not disclose a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as required by amended claim 24. Accordingly withdrawal of this rejection is respectfully requested.

B. There is no suggestion or motivation to modify the cited reference

Reconsideration of this rejection, in light of the amendment to claim 24, is also respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness because there is no suggestion or motivation disclosed by the Reaux publication for one of ordinary skill in the art of cast and splint construction to construct a liner having a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as is required by amended claim 24.

As discussed above in section 2, the liner disclosed in the Reaux publication allows the passage of vapors and gasses therethrough in order to wick away perspiration from the user, or to keep the user's skin dry. Because the liner of the Reaux publication is meant to be used in a cast or splint, to be worn for weeks or months at a time, the Reaux publication actually teaches away from providing the liner with a continuously cured silicone elastomeric layer such that the liner is vapor impervious. This is because a liner that is impervious to vapors and gasses, and is used with the casts or splints of the Reaux publication, would trap the perspiration of the user, causing discomfort and possibly skin rashes, and further would trap odors within the cast or splint.

Accordingly, a *prima facie* case of obviousness cannot stand since there is no suggestion or motivation in the Reaux publication, and in fact the Reaux publication actually teaches away from providing a liner having a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as is required by amended claim 24. Accordingly, withdrawal of this rejection is respectfully requested.

C. There is no reasonable expectation of success

Reconsideration of this rejection, in light of the amendment to claim 24, is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness because there is no reasonable expectation of success for replacing the liner of the Reaux publication with a liner having a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as required by amended claim 24.

For many of the reasons discussed above, replacing the liner of the Reaux publication with a liner having a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as required by amended claim 24, would destroy the function of the liner of the Reaux publication. Because the liner of the Reaux publication is intended to be used with a cast or splint, and is meant to be worn for weeks or months at a time, a continuously cured silicone elastomeric layer such that the liner is vapor impervious would destroy the requirement that the liner either wick

away a user's perspiration or keep the user's skin dry. Since there are legitimate health issues, such as skin rashes, that would arise from the use of a liner that is impervious to vapors and gasses there is no reasonable expectation of success in providing a continuously cured silicone elastomeric layer to the liner of the Reaux publication, such that the liner is vapor impervious.

Thus, a *prima facie* case of obviousness cannot stand since there is no reasonable expectation of success for providing a liner having a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as required by amended claim 24, in place of the liner of the Reaux publication.

For all of the above reasons, the rejection's reliance on *In re Leshin*, 125 USPQ 416, (CCPA 1960), is misplaced. Because the selection of a liner having continuously cured silicone elastomeric layer such that the liner is vapor impervious, as required by amended claim 24, would destroy the function of the liner of the Reaux publication, it would not have been a material suitable for the intended use of the liner of the Reaux publication. Hence, the selection of a liner having continuously cured silicone elastomeric layer such that the liner is vapor impervious, as required by amended claim 24, would not have been a matter of obvious design choice. Accordingly, withdrawal of this rejection is respectfully requested.

4. Rejection of claims 13-20 and 22-25 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent 5,228,164 (Graf et al.) in view of the Reaux publication

Reconsideration of this rejection, in light of the amendments to claims 13 and 24, is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness.

A. None of the cited references disclose every limitation of the claims

Reconsideration of this rejection, in light of the amendments to claims 13 and 24, is respectfully requested on the basis that the rejection fails to establish a *prima*

facie case of obviousness because none of the cited references disclose every limitation of pending claims 13-20 and 22-25.

The rejection acknowledges that the Graf et al. patent fails to disclose a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, as required by amended claim 13 (page 4, line 16). The rejection also acknowledges that the Graf et al. patent fails to disclose a liner having a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as required by amended claim 24 (page 5, lines 1-2).

As discussed above in sections 2 and 3, the Reaux publication fails to disclose both a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, as required by amended claim 13, and a liner having a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as required by amended claim 24.

Because none of the cited references disclose every limitation of claims 13-20 and 22-25, a *prima facie* case of obviousness cannot stand. Accordingly, withdrawal of this rejection is respectfully requested.

B. There is no suggestion or motivation to combine the cited references

Reconsideration of this rejection, in light of the amendments to claims 13 and 24, is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness because there is no suggestion or motivation, for one of ordinary skill in the art of last construction, to combine the cited references in order to construct a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, or a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as is required by amended claims 13 and 24 respectively.

As previously discussed in sections 2 and 3 above, the Reaux publication fails to provide any suggestion or motivation, and in fact actually teaches away from, constructing a liner that is vapor impervious and having a generally non-porous

surface formed from a continuously cured elastomer, or a continuously cured silicone elastomeric layer such that the liner is vapor impervious.

The Graf et al. patent fails to provide any suggestion or motivation to construct a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, or a continuously cured silicone elastomeric layer such that the liner is vapor impervious. The Graf et al. patent uses a polyester, knit stockinette, which is inherently porous and allows the passage of vapors and gasses therethrough, as a liner to protect the foot and ease removal of the shell (col. 8, line 67; col. 9, lines 1-2). There is a disclosure that other materials can be used to protect the foot, but all of the suggested materials are lubricants applied directly to the skin of the wearer (col. 9, lines 2-6).

Nowhere in the Graf et al. patent is there any suggestion to use a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, or a continuously cured silicone elastomeric layer such that the liner is vapor impervious.

Accordingly, a *prima facie* case of obviousness cannot stand since there is no suggestion or motivation to combine the cited references in order to construct a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, or a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as is required by amended claims 13 and 24. Therefore, withdrawal of this rejection is respectfully requested.

C. There is no reasonable expectation of success

Reconsideration of this rejection, in light of the amendments to claims 13 and 24, is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness because there is no reasonable expectation of success that a combination of the cited references will disclose a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, or a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as is required by amended claims 13 and 24, respectively.

For the reasons discussed above, a combination of the Graf et al. patent and the Reaux publication, will fail to disclose a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, or a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as is required by amended claims 13 and 24.

Thus, a *prima facie* case of obviousness cannot stand since there is no reasonable expectation that the combination of the of the cited references will successfully disclose a liner that is vapor impervious and having a generally non-porous surface formed from a continuously cured elastomer, or a continuously cured silicone elastomeric layer such that the liner is vapor impervious, as is required by amended claims 13 and 24.

Again, the rejection's reliance on *In re Leshin*, 125 USPQ 416, (CCPA 1960), is misplaced. In the case of *In re Leshin*, the prior art was a container made from plastic and the applicant was claiming a different plastic. Here, the liners of the Reaux publication and the Graf et al. patent are not made from any kind of non-porous elastomer that is impervious to vapors and gasses. Therefore, it would not have been obvious, in view of *In re Leshin*, to use a non-porous, continuously cured elastomer or silicone that is impervious to vapors and gasses, as required by amended claims 13 and 24, because the prior references do not disclose any kind of non-porous elastomer that is impervious to vapors and gasses.

Accordingly, withdrawal of this rejection is respectfully requested.

5. Conclusion

As a result of the amendment to the claims, and further in view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is respectfully requested that every pending claim in the present application be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the applicants' attorney, the examiner is invited to contact the undersigned at the numbers shown below.

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